Common Issue Expert Report of Lloyd R. Saberski. M.D.

I, Lloyd Saberski, am Board Certified in internal medicine, anesthesiology, and pain management, with an unrestricted license to practice medicine in the State of Connecticut. My qualifications are set forth in my attached *Curriculum Vitae.* I have experience with managing ambulatory surgical procedure facilities within pain management practices which are functionally similar to the ambulatory center facilities involved in these NECC cases. I have experience working with compounding pharmacies and prescribing compounded medications. I also am aware of the risks and consequences of using adulterated products based on my training, experience and research.

I have reviewed the medical records of John C. Millhausen, Edna C. Young, Teresa A. Davis, Belinda L. Dreisch, Angela Farthing, Bahman Kashi, Linda J. Torbeck and Brenda Lee Rozek, as well as other records relating to them, and I have formed the opinions stated below to a reasonable degree of medical probability.

The records I reviewed were from:

1. Ritu T. Bhambhani, MD and Box Hill Surgery Center
2. Upper Chesapeake Medical Center
3. Johns Hopkins Hospital
4. Johns Hopkins Hospital Bayview Medical Center
5. University of Maryland Medical Center
6. Union Hospital records
7. St. Joseph Medical Center
8. Greater Baltimore Medical Center
9. Mercy Hospital of Folsom
10. Mercy General Hospital
11. Upper Chesapeake Medical Center
12. Franklin Square Hospital
13. Kernan Hospital
14. Gilchrist Hospice Care, Inc.
15. State of Maryland Death Certificate
16. George Washington Spine and Pain Center
17. Express Care
18. UC Davis Health System
19. CDC – CSF Specimen
20. Sacramento County Death Certificate
21. Donlin Long, MD
22. George Washington Spine and Pain Center
23. Maryland Department of Health & Mental Hygiene ("DHMH")

I have also reviewed the depositions of Dr. Bhambhani, Box Hill Nurse Andrew Vickers, and Lucy Wilson, M.D. MD, Sc.M., Chief of DHMH's Center for Surveillance, Infection Prevention and Outbreak Response.

Briefly: All eight of the individuals listed above were evaluated and treated by Dr. Ritu T. Bhambhani at Box Hill Surgery Center in 2012. Every one of the patients received injections with a preservative-free compounded formulation of methylprednisolone acetate ("MPA") obtained from compounding pharmacy New England Compounding

Center ("NECC"). The MPA in all of these cases was dispensed from vials from recalled lots of NECC's MPA, which state and federal government agencies found contaminated with fungus.

All of the above-listed patients developed serious life threatening fungal infections or were treated for suspected life-threatening fungal infections. These infections included fungal meningitis and spinal abscess. Four of the eight patients died from their infections (John C. Millhausen, Edna C. Young, Bahman Kashi, and Brenda Lee Rozek). According to DHMH records and testimony of Dr. Wilson, the four death cases were each determined by the Maryland Department of Health and Mental Hygiene ("DHMH") to be confirmed infection cases associated with the 2012 NECC fungal infection outbreak DHMH investigated along with the Center for Disease Control and other State health agencies. The other four patients (Teresa A. Davis, Belinda L. Dreisch, Angela Farthing and Linda J. Torbeck) continue to this day with complications derived from their fungal infections and or treatments from the fungal infections.

Discussion: The standards of practice for pain management, pain management injections and compounding of medications for use in medical practices are the same throughout the United Sates.

Therapeutic steroid injections have been utilized in medicine routinely for years, including spinal injections with corticosteroids. The standard of care requires that any injectable substance that a physician utilizes be safe, sterile, and prepared to accepted industry standards. Steroids, both with and without preservatives, utilized for injection are commercially available from various manufacturers and meet the U.S. Food & Drug Administration ("FDA") requirements as to purity and strength.

In the cases of John C. Millhausen, Edna C. Young, Teresa A. Davis, Belinda L. Dreisch, Angela Farthing, Bahman Kashi, Linda J. Torbeck and Brenda Lee Rozek, the steroids used were from NECC, a compounding pharmacy. NECC essentially manufactured and dispensed methylprednisolone acetate that purportedly was without preservative in single and in multi-dose volume vials. Through government investigations it has been found that lots of methylprednisolone acetate compounded at NECC in the spring and summer of 2012 were contaminated with various organisms, including fungi. Regrettably, the presence of contaminants, including fungi, when injected into patients like John C. Millhausen, Edna C. Young, Teresa A. Davis, Belinda L. Dreisch, Angela Farthing, Bahman Kashi, Linda J. Torbeck and Brenda Lee Rozek, caused potentially life-threatening infections.

If a physician wants a product from a compounding pharmacy, it must be because he or she is treating a patient with a specific need that cannot be fulfilled by a FDA approved manufactured product. If there are FDA approved products that can fulfill the need, then there would be no need for compounding a product. In this group of cases Dr. Bhambhani and Box Hill Surgery Center utilized a NECC compounded MPA which was benzyl alcohol-free when there were FDA approved benzyl alcohol-free deposit steroids available. Thus, there was no need to even consider the use of a compounded steroid

preparation. Doing so in my opinion violated the standard of care applicable both to prescribing physicians and ambulatory care/procedure clinics.

From my review of Dr. Bhambhani's deposition testimony, she and Box Hill Surgery Center mistakenly thought that the preservative-free MPA from NECC was safer than FDA approved products presumably out of concern that preservatives could be injurious and cause arachnoiditis. However, epidural injections are not into the sub-arachnoid space and are not implicated with arachnoiditis. Furthermore, epidural injections of steroids with preservative had been shown to be safe, not causative of arachnoiditis by the mid-2000s, years before Dr. Bhambhani and Box Hill Surgery Center injected the patients listed above. Thus, there was not even a legitimate medical reason to consider using preservative-free MPA for an epidural injection in 2012.

The MPA product made by NECC and presumed to be preservative-free was actually only benzyl alcohol-free. It however contained other preservatives, including polyethylene glycol (PEG), which had been widely implicated as a cause of arachnoiditis when injected into the sub-arachnoid space. Thus, every one of the patients injected by Dr. Bhambhani, at the Box Hill Surgery Center received MPA containing PEG; the product injected was not truly preservative-free.

If Dr. Bhambhani and Box Hill Surgery Center had a legitimate medical or scientific reason for ordering compounded MPA from NECC (which in my opinion they did not), they were required under Maryland and Massachusetts law to write a prescription specific for their patient and their patient's special needs. Dr. Bhambhani never wrote a prescription for MPA for any particular patient with a patient-specific special need, which was a violation of the applicable standards for working with compounding pharmacies.

Another wrong and troubling action was Box Hill's and Dr. Bhambhani's purchasing MPA for a particular patient and administering the MPA to a different patient. The MPA that was made available to Dr. Bhambhani and Box Hill Surgery Center from NECC was shipped in bulk quantities, was not patient specific and did not have any specification for patient special needs. This too violated the applicable standards for working with compounding pharmacies. Apparently, a list of names of prior patients who had already received MPA at Box Hill was sent to NECC to order multiple bottles of MPA for each patient listed. Prior to the public announcement of the outbreak, Dr. Bhambhani and Box Hill Surgery Center also obtained vials of NECC preservative free MPA from Harford County Ambulatory Surgical Center, with whom Dr. Bhambhani had an association, to fill in for already on-hand NECC MPA Dr. Bhambhani decided to not use in September 2012 after learning of two Box Hill Surgery Center patients developing serious infections (one fatal) following their steroid injections at Box Hill. The use of such list (or obtaining the transfer of MPA vials from Harford County Ambulatory Surgical Center to Box Hill Surgery Center) was not a patient-specific prescription. The list or NECC order form also did not indicate any special need for a compounded preparation. The patients named on the list submitted to NECC by Dr. Bhambhani and Box Hill Surgery Center (and Harford County Ambulatory Center as to the transferred vials) most likely did not receive any of

the steroids dispensed and shipped by NECC purportedly for administration to them. For example, an examination of the timing of the office and procedure visits of Brenda Rozek readily bears out that she was administered NECC MPA in late August 2012 that was dispensed by NECC for a prior Box Hill Surgery Center patient.

There also is no indication Dr. Bhambhani prior to the infection outbreak in 2012 discussed with this group of Box Hill Surgery Center patients the fact she was administering a steroid medication that was made by a compounding pharmacy and the risks and benefits of using a compounded and not FDA approved manufactured steroid product. It is likely that Dr. Bhambhani did not discuss the fact that she was administering compounded medication with her patients because she mistakenly thought NECC compounded products were FDA approved. This erroneous understanding is inexcusable and denied her patient the opportunity to give an informed consent to the procedures. All of this conduct violated the standard of care applicable to both pain physicians and ambulatory care/procedure clinics.

Opinions: Based on my review of the above materials and my knowledge, training, and experience, it is my opinion, within a reasonable degree of medical probability or certainty, that health care providers Dr. Ritu Bhambhani and Box Hill Surgery Center were negligent and violated the applicable standards of care by:

1. Failing to exercise reasonable and prudent care to ensure that the steroid preparations used for injections were sterile, free of contaminants, and compounded in accordance with all applicable industry standards.

2. Failing to exercise real and prudent care to ensure that the drugs purchased for therapeutic injections into John C. Millhausen, Edna C. Young, Teresa A. Davis, Belinda L. Dreisch, Angela Farthing, Bahman Kashi, Linda J. Torbeck and Brenda Lee Rozek were purchased from a drug manufacturer or compounder that reliably and consistently utilized proper quality control, safety, and sterility measures so as to minimize or eliminate the possibility that the drugs were not sterile or contaminated.

3. Failing to exercise reasonable care to avoid injecting John C. Millhausen, Edna C. Young, Teresa A. Davis, Belinda L. Dreisch, Angela Farthing, Bahman Kashi, Linda J. Torbeck and Brenda Lee Rozek with contaminated drugs.

4. Failing to purchase and administer a multi-dose steroid preparation with the preservative benzyl alcohol, such as Depo-Medrol, for therapeutic injections, as opposed to injecting John C. Millhausen, Edna C. Young, Teresa A. Davis, Belinda L. Dreisch, Angela Farthing, Bahman Kashi, Linda J. Torbeck and Brenda Lee Rozek with benzyl alcohol-free methylprednisolone acetate.

5. Failing to have a basic understanding of the difference between a compounding pharmacy and FDA approved manufacturers and thus failing to properly inform John C. Millhausen, Edna C. Young, Teresa A. Davis, Belinda L. Dreisch, Angela Farthing, Bahman Kashi, Linda J. Torbeck and Brenda Lee Rozek that the steroid medication sold and administered to them was not the FDA approved drug Depo-Medrol but, rather, was a non-FDA approved formula, namely, a compounded benzyl alcohol -free methylprednisolone acetate.

6. Failing to discuss with and warn John C. Millhausen, Edna C. Young, Teresa A. Davis, Belinda L. Dreisch, Angela Farthing, Bahman Kashi, Linda J. Torbeck and Brenda Lee Rozek of the risks and dangers associated with the injection of compounded benzyl alcohol -free steroid medication, including increased risk of infection.

7. Negligently using benzyl alcohol preservative-free multi-dose vials of steroidal preparations rather than single-dose vials.

8. Incorrectly documenting that Depo-Medrol was the steroid sold to these patients and used when compounded benzyl alcohol -free methylprednisolone acetate was utilized.

9. Failing to comply with applicable statutes, regulations or guidelines governing the prescription and dispensing of compounded prescription medication for patients.

In conclusion, there was no medical or scientific justification for Dr. Ritu Bhambhani and Box Hill Surgery Center to even consider the use of compounded MPA in 2012. The means by which Dr. Ritu Bhambhani and Box Hill Surgery Center procured MPA from NECC and used it for patients without a patient specific prescription was a violation of law and subverted normal protections found with FDA approved products. The substitution of NECC's compounded MPA instead of a FDA approved steroid added considerable risk of infection without any known potential benefit. The risks should have been disclosed to and discussed with the patients prior to their procedures.

It is my opinion, to a reasonable degree of medical probability or certainty, that, as a direct and proximate result of the violations of the standard of care by Dr. Ritu Bhambhani and Box Hill Surgery Center as described above, John C. Millhausen, Edna C. Young, Teresa A. Davis, Belinda L. Dreisch, Angela Farthing, Bahman Kashi, Linda J. Torbeck and Brenda Lee Rozek developed and were treated for fungal infections and/or suffered fungal infection, which have been associated with multiple complications, either directly from the infection or from the treatments for the infection. In addition, to a reasonable degree of medical probability, the deaths of John C. Millhausen, Edna C. Young, Bahman Kashi, and Brenda Lee Rozek were the direct and proximate result of violations of the standard of care by Dr. Ritu Bhambhani and Box Hill Surgery Center.

Exhibits:	None.
Expert Qualifications:	Please see appendix for CV.
Trials & depositions:	Please see appendix for list of trials and depositions.
Compensation:	Please see appendix for fee sheet

I reserve the right to supplement my opinions after further research, review of additional documents, articles, depositions, etc.

Lloyd Saberski, MD
Board certified Internal Medicine
Board certified Anesthesiology
Fellowship trained pain management specialist
Board certification / added qualification in Pain Management

Faculty Yale School of Medicine
Department of Medicine
Palliative & Supportive Care

Faculty University of Connecticut School of Medicine
Department of Medicine

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